Outcomes of interventions for recurrent disease after endoluminal intervention for superficial femoral artery disease

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Background: **Aggressive endoluminal therapy for superficial femoral artery (SFA) occlusive disease is commonplace, but the outcomes of current management of recurrent disease have not been well defined. This study examined the outcomes of endoluminal and open interventions for recurrent SFA disease.**

Methods: **A database of patients undergoing endovascular treatment of the SFA between 1986 and 2008 was retrospectively queried, and those with recurrent disease were selected. Outcomes were determined by Kaplan-Meier survival analyses, and the Cox proportional hazard model was used for time-dependent variables.**

Results: **Symptomatic SFA disease resulted in endovascular treatment in 735 limbs in 631 patients (64% male; average age, 67 years). The restenosis rate was 16% ± 3% at 5 years. Restenosis developed in 222 patients, of whom 58 remained asymptomatic and 164 underwent repeat intervention comprising percutaneous transluminal angioplasty (PTA) in 59% and bypass in 41%. Bypass was used for critical ischemia (rest pain/tissue loss: 52% repeat PTA vs 75% bypass) and in more extensive recurrent disease (TransAtlantic Inter-Society Consensus [TASC] II C/D lesions: 42% repeat PTA vs 67% bypass). Primary and repeat PTA had mean ± standard error of the mean equivalent cumulative patency (73% ± 9% vs 73% ± 3% at 5 years) and duration of symptom relief (66% ± 3% vs 63% ± 6%). Bypass had significantly superior outcomes for patency (93% ± 8%) and symptom relief (81% ± 8%), but morbidity was 28% vs 16% for PTA. Critical ischemia, TASC-II lesion (C/D), and one-vessel tibial runoff were significant predictors of failure in the repeat PTA group.**

Conclusions: **Reintervention is required in a minority of patients selected for SFA angioplasty. Bypass for recurrent disease is used more commonly for extensive disease and is associated with superior long-term outcomes but higher mortality. Bypass rather than repeat PTA may be the better strategy for progressive, complex recurrent disease. (J Vasc Surg 2010; 52:331-9.)**

Endoluminal therapy for superficial femoral artery (SFA) occlusive disease is now commonplace, and the techniques have diffused throughout the interventional and surgical community.[1,2] The technology and technical skills in practice have permitted more and more challenging lesions to be tackled,[3,4] and this progress can be charted in the changes made in the recommendations for SFA occlusive disease between the Trans-Atlantic Inter-Society Consensus (TASC) I[5] and TASC-II documents.[6] Multiple reports have demonstrated that presenting symptoms, diabetes, and runoff will affect the anatomic and functional outcomes after SFA intervention.[7-11] Furthermore, an uncomplicated failed intervention does not appear to compromise subsequent surgery and long-term outcomes.[12,13]

With the increasing volume of SFA interventions has come an increase in repeat interventions for recurrent disease. Early articles on this subject suggested that these interventions did not fare as well as the primary intervention.[13,14] Since these reports were published, additional technologies have been made available and different approaches have been taken for reinterventions on recurrent SFA lesions.[3,4] The aim of this study was to examine the outcomes of endoluminal and open interventions for recurrent SFA disease.

METHODS

Study design. A database of patients undergoing endovascular treatment of SFA between 1986 and 2008 was retrospectively queried, and those with recurrent disease were selected. Three groups were developed: primary endo, those undergoing primary endovascular SFA intervention; repeat endo, those undergoing repeat endovascular SFA intervention for recurrent disease; and bypass, those who underwent bypass surgery for recurrent disease after a primary SFA intervention. Methodology, definitions of comorbidities and outcomes are shown in the Appendix (online only). Data utilization fell under the category of secondary use of preexisting data as defined by the Institutional Review Board and Health Insurance Portability and Accountability Act.

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Table I. Characteristics of patients

Demographics	*Primary endo*	*Repeat endo*	*Bypass*	P *value*
Limbs treated, No.	735	96	68	. . .
Male, %	66	65	63	.87
Age, mean ± SD, y	67 ± 12	67 ± 13	66 ± 12	.81
Symptoms, %				
Claudication	61	48	25	.02
Rest pain	16	19	28	
Tissue loss	23	33	47	
Comorbidities				
Smoking history	78	85	67	.023
Current smoker	18	11	24	.12
CAD	47	65	82	.001
Hypertension	89	93	95	.13
Diabetes	51	58	56	.34
Hyperlipidemia	65	66	71	.64
Metabolic syndrome	57	61	74	.023
Cerebrovascular	13	11	15	.83
CKD	23	20	20	.88
Hypothyroidism	11	11	9	.84
Hypercoagulability	6	8	4	.55

CAD, Coronary artery disease; *CKD*, chronic kidney disease; *SD*, standard deviation.

Statistical analysis. All statistical analyses were performed on an intention-to-treat basis. Measured values are reported as percentages or means ± standard deviation. Patency and limb salvage rates were calculated using Kaplan-Meier analysis and reported using current Society for Vascular Surgery (SVS) criteria.[15] Kaplan-Meier analyses are reported with standard errors. Cox proportional hazard analyses and univariate and multivariate analyses were performed to identify factors associated with outcomes. Analyses were performed using JMP 7.0 software (SAS Institute, Cary, NC).

RESULTS

Patient population. A total of 735 limbs in 631 patients (64% male; average age, 67 years) underwent endovascular treatment for symptomatic SFA disease. In the primary endo group (Table I), 61% of these interventions were for lifestyle-limiting claudication. The restenosis rate was 16% ± 3% at 5 years. By Cox proportional hazards analysis, the development of restenosis was associated with the presence of metabolic syndrome (relative risk [RR], 1.33; $P = .004$), hemodialysis (RR, 1.72; $P = .003$), critical limb ischemia (RR, 1.28; $P = .001$), TASC C/D lesions (RR, 3.86; $P = .001$), poor tibial runoff (RR, 1.24; $P = .001$), and poor clinical response to intervention, defined as lack of resolution of symptoms or <1-point rise in SVS/Rutherford classification (RR, 2.23; $P = .03$).

Restenosis developed in 222 patients, of whom 58 remained asymptomatic, and 164 underwent repeat interventions consisting of 59% percutaneous (repeat endo) and 41% bypass procedures (Table I). Age and gender were equivalent in the repeat endo and bypass groups. Smoking history was more prevalent in both endovascular groups, and current smoking was more prevalent in the bypass group than in the endo groups (Table I). The bypass group had a higher prevalence of coronary artery disease and metabolic syndrome than either endo group (Table I). The three groups had an equal prevalence of hypertension, hyperlipidemia, diabetes, and chronic renal disease (Table I). Approximately 60% of patients in each group were taking statins. Equal percentages of patients had insulin-dependent and non-insulin-dependent diabetes, and an equal number required hemodialysis.

Presentation of recurrent disease was dissimilar to the initial presenting symptoms in the primary endo group. The repeat endo group had more critical ischemia than the primary endo group, whereas the bypass group had more tissue loss (Table I). When each patient cohort was examined, the distribution of symptoms from initial presentation to repeat presentation was similar in the group treated with repeat endovascular intervention; however, there was a marked progression of presentation of disease in those who required bypass (Fig 1, *A*).

Anatomy. Patients presenting with recurrent disease and undergoing repeat endo had a similar distribution of TASC-II lesions as did the primary endo group, whereas those undergoing bypass had a greater number of TASC-II C and D lesions (Table II). Repeat endo was used for the entire range of restenosis categories (1-4), with more than half being occlusive. Bypass surgery was nearly exclusively used for III and IV restenosis categories (Table II).

When traditional runoff scores and a modified SVS runoff score were used to grade the runoff, there was no difference in the group averages among primary endo, repeat endo, and bypass (Table II). When each patient cohort was examined, the distribution of TASC-II lesions at the initial presentation and the repeat presentation was similar in the group treated with repeat endovascular intervention, whereas lesions were more advanced and had progressed in those undergoing bypass (Fig 1, *B*). A similar comparison undertaken for runoff showed that runoff was worse in the patients who underwent repeat endovascular intervention compared with the initial runoff score but had markedly deteriorated in those who required bypass for recurrent disease (Fig 1, *C*).

Immediate outcomes. The technical failure rates were 3% for primary endo and repeat endo and 0.5% for bypass. Treatment modality did not influence outcome in the repeat endo group. However, >50% of the lesions in the repeat endo group required recannulization compared with the primary endo group, and about 60% of the repeat endo group underwent advanced techniques, including primary stenting, atherectomy, and concomitant tibial angioplasty to re-establish satisfactory anatomic results (Table III). This was a switch from the primary endo group interventions, where more iliac concomitant interventions were performed, but would be consistent with the finding that runoff had worsened in this group. In the bypass group, there was an equal distribution of femoral above-knee to popliteal, below-knee to popliteal, and tibial bypasses with increasing use of vein as we moved down the leg. Endoscopic vein harvest was used in one-third of the cases.

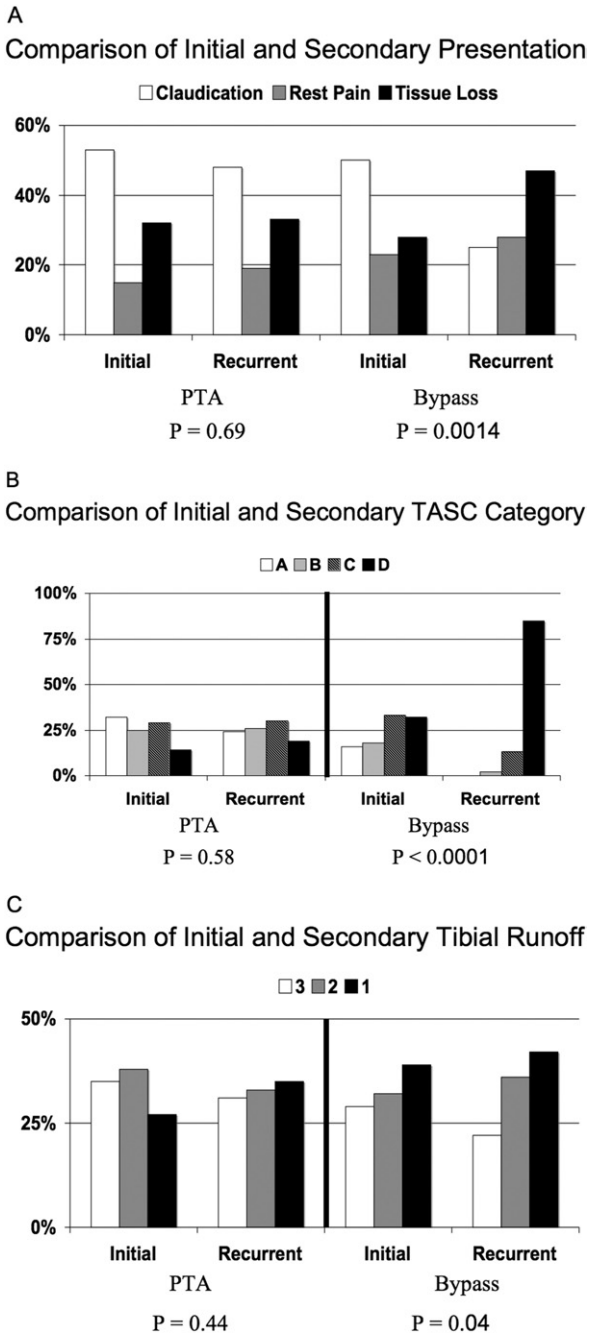


Fig 1. Difference in **(A)** symptom presentation, **(B)** TransAtlantic Inter-Society Consensus *(TASC)* II lesion category, and **(C)** tibial runoff of patients presenting with recurrent symptoms who underwent repeat percutaneous transluminal angioplasty *(PTA)* or bypass.

Mortality was equivalent across the groups despite the increased burden of coronary disease in the bypass group. Morbidity was similar between the primary endo and the repeat endo groups but was greater in the bypass group, being mainly driven by an increase in local complications, predominantly wound-related (Table IV).

Table II. Lesion characteristics

Characteristic	*Primary endo*	*Repeat endo*	*Bypass*	P *value*
TASC-II category, %				
A/B	62	58	33	.001
C/D	38	42	67	
Restenosis grade, %				
1		14	0	.001
2		18	1	
3		15	50	
4		53	49	
Runoff, mean ± SD				
Tibial vessels, No.	2.0 ± 0.8	2.0 ± 0.8	1.9 ± 0.8	.61
Modified SVS runoff score	6.2 ± 4.2	5.9 ± 4.3	6.5 ± 4.1	.66

SD, Standard deviation; *SVS,* Society for Vascular Surgery; *TASC,* TransAtlantic Inter-Society Consensus.

Table III. Procedures, complexity, hemodynamic changes, and immediate symptom relief

A, *Endovascular group*

Procedure	*Primary endo*	*Repeat endo*	P *value*
Intervention, %			
Recannulization	26	55%	<.001
Angioplasty	69	41%	.0003
Primary stenting	16	28%	
Laser/directional atherectomy	15	31%	
Stent usage	25	31%	.21
Adjunctive interventions, %			
Aortoiliac intervention	10	6	.27
Tibial intervention	3	17	<.001
Complexity score	1.2 ± 0.5	1.3 ± 0.5	.07

B, *Bypass group*

	Bypass	*Vein*[a]	*Endovein*[b]
Fem AK pop, %	35	25	33
Fem BK pop, %	32	50	18
Fem tibial, %	32	85	40

Endovein, Endoscopic vein harvest; *Fem AK pop,* femoral to above knee popliteal; *Fem BK pop,* femoral to below knee popliteal.
[a]$P < .001$; [b]$P < .001$.

Hemodynamically, there was a marked increase in ankle-brachial indexes (ABIs) across all three groups, with >70% of patients having a rise in their ABI of >0.15. After primary endo intervention, 82% of patients were considered to have improved or resolved symptoms. This dropped to 54% in the repeat endo group, with a significantly greater number of patients showing no change in symptoms. In the bypass group, 95% were considered to have improved or resolved symptoms.

Short-term clinical efficacy, which was defined as absence of recurrent symptoms for 1 year, patency of the intervention until wound healing, limb salvage for 1 year, maintenance of ambulation for 1 year, and survival for 1 year, was 64%, 65%, and 67% in the primary endo, the

Table IV. Outcomes

Outcome	*Primary endo*	*Repeat endo*	*Bypass*	P *value*
Mortality, %	1	2	0	.39
Morbidity, %	16	16	28	.04
Systemic, %	3	4	3	.82
Local, %	13	12	25	.02
Hemodynamic changes				
ABI change, mean ± SD	0.26 ± 0.28	0.32 ± 0.23	0.40 ± 0.24	.98
ABI increase >0.15, %	70	72	79	.25
Immediate symptom relief				.0001
Resolved, %	49	28	60	
Improved, %	33	28	35	
No change, %	16	41	3	
Deterioration, %	1%	3	1	
Amputation				.81
Toe and/or forefoot, %	2	2	1	
Below knee, %	8	4	9	
Above knee, %	4	6	4	

ABI, Ankle-brachial index; *SD,* standard deviation.

repeat endo, and the bypass group, respectively ($P = .73$). There was no significant association with early failure (<6 months) in the primary endo group and early failure in the repeat endo group ($P = .23$). There was, however, a significant association with early failure (<6 months) in the primary endo group and early failure in the bypass group ($P = .0002$).

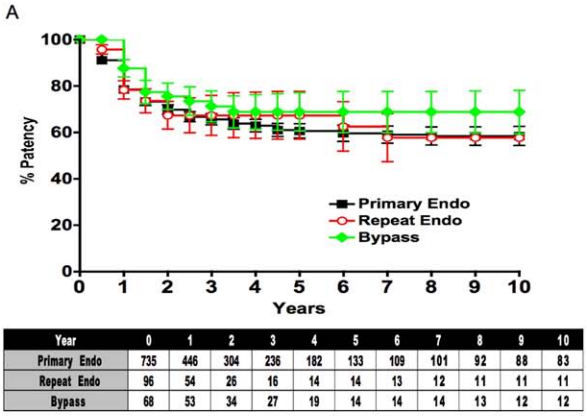
Long-term anatomic outcomes. There was no significant difference in the primary patency of the primary endo and the repeat endo groups (Fig 2, *A*). The primary patency of the bypass group was also equivalent to both endo groups, with 5-year rates of 60% ± 3%, 67% ± 10%, and 69% ± 8%, respectively, in the primary endo, repeat endo and bypass groups. Freedom from restenosis at 5 years was 76% ± 3%, 72% ± 9%, and 92% ± 8%, respectively, in the primary endo, repeat endo, and bypass groups (Fig 2, *B*). Assisted primary patency was higher in the bypass group, showing a significant advantage over both endo groups (Fig 2, *C*), with 5-year rates of 73% ± 3%, 74% ± 9%, and 84% ± 10%, respectively, in the primary endo, repeat endo, and bypass groups.

A similar pattern was also seen for secondary patency (Fig 2, *D*), with 5-year rates of 73% ± 3%, 73% ± 9%, and 92% ± 7%, respectively, in the primary endo, repeat endo, and bypass groups. The patients in the repeat endo group underwent up to a maximum of three additional interventions to maintain patency, and 36% of the repeat endo limbs required one additional (second repeat) intervention, 20% a third repeat intervention, and 3% a fourth repeat intervention. Bypass was required in 14% of limbs in subsequent follow-up after a first repeat endovascular intervention and in 17% in subsequent follow-up after the second repeat endovascular intervention.

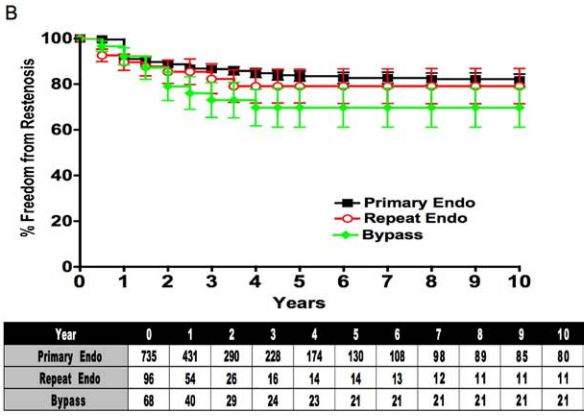
Freedom from target lesion revascularization at 3 years was equivalent in the primary endo and repeat endo groups (57% ± 3% and 60% ± 10%) and superior in the bypass group (69% ± 9%; Fig 2, *E*). The etiology of failure in the bypass group was early occlusion in 87% and conduit failure (multiple stenoses and negative remodeling) in the rest. The etiology of failure in the endo group was a combination of recurrent recalcitrant stenosis (23%), occlusion (50%), and symptomatic hemodynamic failure (27%). There was no significant association with early failure (<6 months) in the primary endo group and ultimate failure in the repeat endo group ($P = .45$). Similarly, there was no significant association with early failure (<6 months) in the primary endo group and ultimate failure in the bypass group ($P = .79$).

By Cox proportional hazards analysis, the primary patency of repeat endo was negatively influenced by the presence of metabolic syndrome (RR, 3.39; $P = .009$) and presenting symptoms (RR, 1.51; $P = .03$).The secondary patency of repeat endo was negatively influenced by presenting symptoms of critical ischemia (RR, 1.76; $P = .01$) and TASC II C/D lesions (RR, 3.10; $P = .046$). Cox proportional hazards analysis also showed the primary patency of bypass was negatively influenced by the presence of a TASC II C/D lesion (RR, 2.78; $P = .001$), presenting symptoms of critical ischemia (RR, 3.40; $P = .04$), and poor runoff (RR, 3.65; $P = .05$). There was an inverse linear trend with respect to presenting symptoms and outcomes, with rest pain and tissue loss negatively influencing the result (χ^2 for trend = 39.441; $P < .0001$). Tissue loss was a poor prognosticator in those with critical ischemia ($P = .023$).

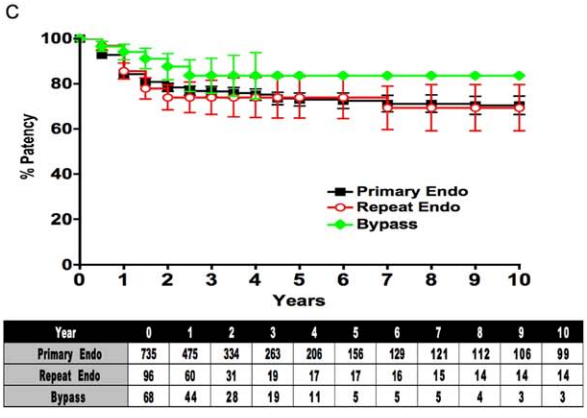
Long-term functional outcomes. Patient survival was 84% ± 3%, 96% ± 5%, and 91% ± 6% at 5 years and 65% ± 4%, 81% ± 10%, and 73% ± 10% at 10 years in the primary endo, repeat endo, and bypass groups, respectively (Fig 3, *A*). Survival was negatively influenced by the presence of congestive heart failure (RR, 1.48; $P = .0038$) and an estimated glomerular filtration rate <60 mL/min/1.73 m^2 (RR, 2.14; $P = .0004$). Runoff, a marker of advanced atherosclerosis, was also associated with decreased survival (RR, 1.81; $P = .0001$). The mortality rate was higher in patients presenting with critical ischemia (RR, 1.76; $P =$



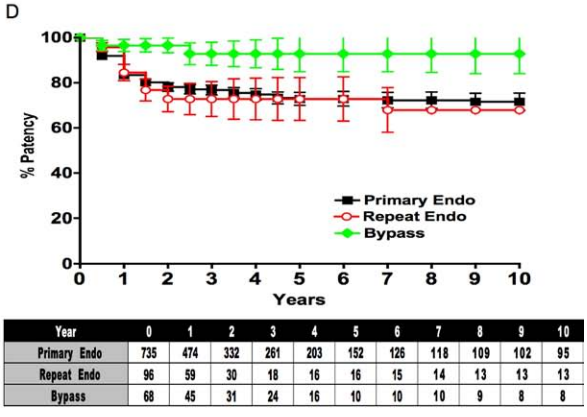
Year	0	1	2	3	4	5	6	7	8	9	10
Primary Endo	735	446	304	236	182	133	109	101	92	88	83
Repeat Endo	96	54	26	16	14	14	13	12	11	11	11
Bypass	68	53	34	27	19	14	14	14	13	12	12



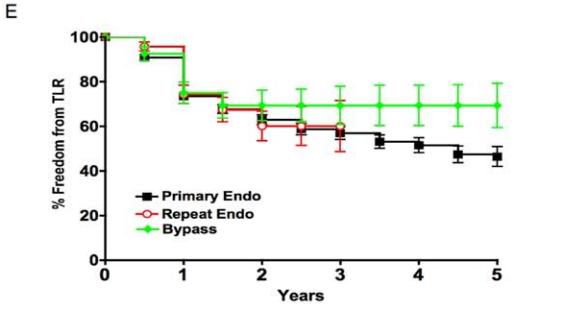
Year	0	1	2	3	4	5	6	7	8	9	10
Primary Endo	735	431	290	228	174	130	108	98	89	85	80
Repeat Endo	96	54	26	16	14	14	13	12	11	11	11
Bypass	68	40	29	24	23	21	21	21	21	21	21



Year	0	1	2	3	4	5	6	7	8	9	10
Primary Endo	735	475	334	263	206	156	129	121	112	106	99
Repeat Endo	96	60	31	19	17	17	16	15	14	14	14
Bypass	68	44	28	19	11	5	5	5	4	3	3



Year	0	1	2	3	4	5	6	7	8	9	10
Primary Endo	735	474	332	261	203	152	126	118	109	102	95
Repeat Endo	96	59	30	18	16	16	15	14	13	13	13
Bypass	68	45	31	24	16	10	10	10	9	8	8



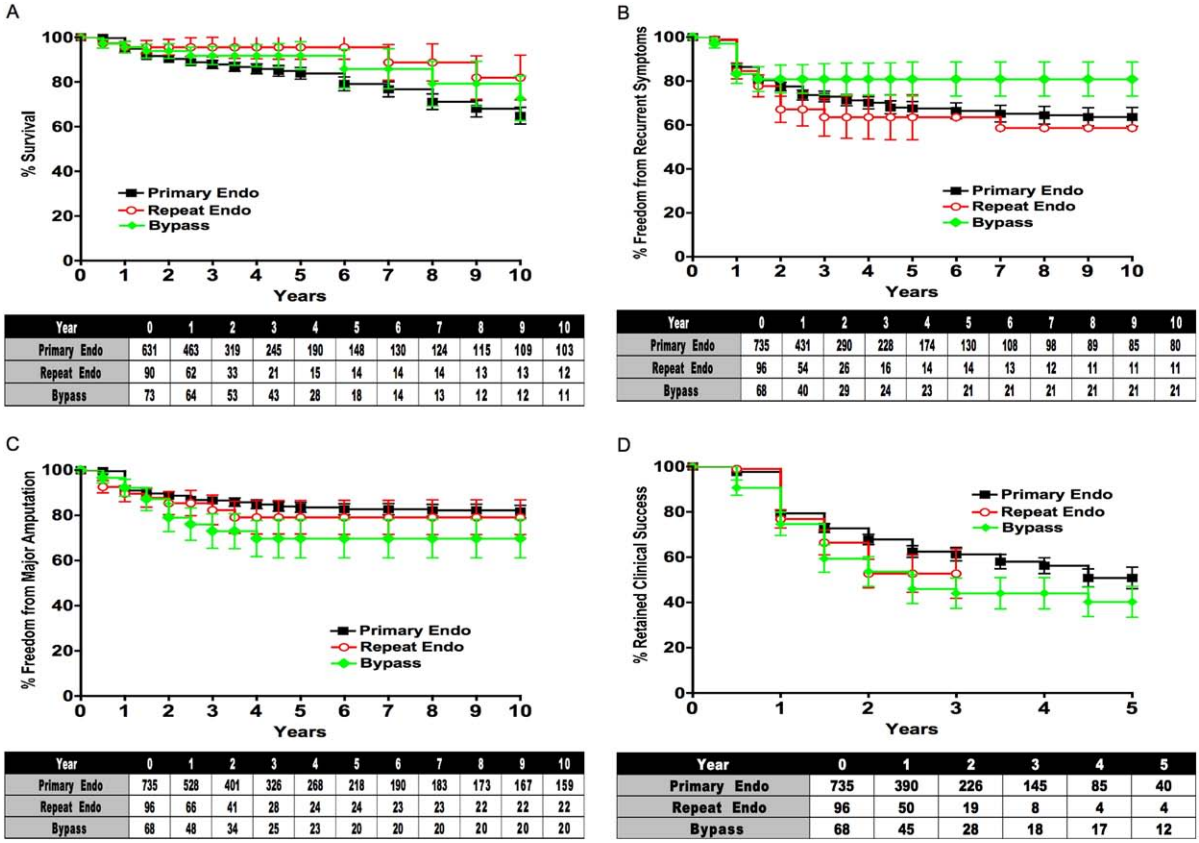
Year	0	1	2	3	4	5
Primary Endo	735	381	218	141	81	40
Repeat Endo	96	50	19	8	5	4
Bypass	68	39	28	23	23	21

Fig 2. Life-table analyses are shown for patients in the primary endo, repeat endo, and bypass groups for (**A**) primary patency, (**B**) freedom from restenosis, (**C**) assisted primary patency, (**D**) secondary patency, and (**E**) freedom from target lesion revascularization. Data are the mean ± standard error of the mean (SEM), and the number of limbs at risk is presented in the Table. No error bars are shown if the SEM is >10%, and the data set terminates if the number at risk is <10.

.001) than in those with claudication. The occurrence of a major amputation was also a negative influence on survival (RR, 1.54; $P = .0002$).

Freedom from recurrent symptoms was superior in the bypass group compared with the endo groups, and there was no significant difference between the endo groups (Fig 3, *B*). The 5-year rate of freedom from recurrent symptoms was 67% ± 3%, 63% ± 9%, and 80% ± 7%, respectively, in the primary endo, repeat endo, and bypass groups ($P = .03$).

Limb salvage was similar between the primary endo, repeat endo, and bypass groups (Fig 3, *C*). The limb-salvage rate was 84% ± 2%, 79% ± 7%, and 69% ± 9% at 5 years and 81% ± 3%, 79% ± 8%, and 70% ± 9% at 10 years,



Year	0	1	2	3	4	5	6	7	8	9	10
Primary Endo	631	463	319	245	190	148	130	124	115	109	103
Repeat Endo	90	62	33	21	15	14	14	14	13	13	12
Bypass	73	64	53	43	28	18	14	13	12	12	11

Year	0	1	2	3	4	5	6	7	8	9	10
Primary Endo	735	431	290	228	174	130	108	98	89	85	80
Repeat Endo	96	54	26	16	14	14	13	12	11	11	11
Bypass	68	40	29	24	23	21	21	21	21	21	21

Year	0	1	2	3	4	5	6	7	8	9	10
Primary Endo	735	528	401	326	268	218	190	183	173	167	159
Repeat Endo	96	66	41	28	24	24	23	23	22	22	22
Bypass	68	48	34	25	23	20	20	20	20	20	20

Year	0	1	2	3	4	5
Primary Endo	735	390	226	145	85	40
Repeat Endo	96	50	19	8	4	4
Bypass	68	45	28	18	17	12

Fig 3. Life-table analysis of patients in the primary endo, repeat endo, and bypass groups for (**A**) survival, (**B**) freedom from recurrent symptoms, (**C**) limb salvage, and (**D**) retained clinical success. Data are the mean ± standard error of the mean (SEM) and number of limbs at risk is presented in the table. No error bars are shown if the SEM is >10%, and the data set terminates if the number at risk is <10.

respectively, in the primary endo, repeat endo, and bypass groups. Major amputations were required in 3%, 2%, and 8% of patients in the primary endo, repeat endo, and bypass groups, respectively, presenting with claudication ($P = .23$), and in 27%, 29%, and 48%, respectively, in patients presenting with critical limb ischemia ($P = .02$).

Retained clinical success, defined as freedom from recurrent symptoms, maintenance of ambulation, and absence of a major amputation, was 61% ± 3%, 53% ± 10%, and 44% ± 7% at 3 years in the primary endo, repeat endo, and bypass groups, respectively (Fig 3, *D*). There was a linear trend with lack of clinical improvement for the repeat endo group ($\chi^2 = 34.44$; $P < .0001$) but not the bypass group ($\chi^2 = 3.228$; $P = .07$), with those presenting with tissue loss more likely than those with rest pain and both more likely than those presenting with claudication. Non-insulin-dependent diabetes mellitus (RR, 1.26; $P = .009$), metabolic syndrome (RR, 1.25; $P = .007$), hemodialysis status (RR, 1.91; $P = .0002$), critical ischemia at presentation (RR, 2.99; $P = .001$), recurrent occlusion (RR, 2.95; $P = .001$), and poor tibial runoff (RR, 1.61; $P = .003$) were the factors negatively affecting freedom from recurrent symptoms and long-term clinical success after reintervention.

DISCUSSION

The current study has demonstrated that repeat interventions for SFA disease are associated with similar short-term and long-term anatomic and functional outcomes to the primary endovascular intervention if there is no progression of disease. However, some of these patients do present with disease progression and loss of runoff between the primary and the repeat intervention; as a result, bypasses were performed in patients with more advanced lesions and poorer runoff. The anatomic outcomes for bypass were superior to outcomes in the primary or the repeat endo groups, despite the worsened anatomic classification and runoff. Clinical outcomes did not match patency outcomes, with no significant difference among the repeat endo and bypass groups.

Patient survival during the study period was very good in all groups and exceeded many previously published reports.[7,16,17] Our study found congestive heart failure and hemodialysis, both end-organ diseases, were negative prog-

nostic factors for survival. Similarly, critical limb ischemia, poor runoff, and major amputation, all surrogate markers of advanced atherosclerosis, were also associated with increased mortality. Statin administration did not influence survival. A disappointing finding was that the penetration of statin therapy was only 60% in the three cohorts and fell below the national guidelines.[18]

Restenosis and reocclusion are common in lower extremity interventions. The failure rate through restenosis and occlusion was 40% ± 3% at 5 years. There was no significant difference in the groups with regard to age and gender. Several risk factors, such as current smoking and metabolic syndrome, were more prevalent in the bypass group than in the repeat endo group. In addition, the anatomic features of the lesion, according to TASC-II category and runoff, were worse in the bypass group than in the repeat endo group. The finding that runoff worsens after intervention is not unique and was reported before by McLafferty et al.[19]

We found that the presence of metabolic syndrome and hemodialysis status, advanced lesions, poor runoff, and presentation with critical ischemia were predictive factors for failure. These factors have also been associated with bypass failure and are consistent with those of other work on SFA interventions.[8,9,20-22] In the bypass group, patient gender, age, indication for surgery, diabetes mellitus or renal disease, and vein graft conduit type were not predictive of the need for subsequent revision.[20] Bypass grafts that required revision because of early lesions (<6 months from index graft placement) were more likely to require an additional revision procedure.[20] We did find a similar relationship between early failure of SFA intervention and early failure of the reintervention (endovascular or bypass).

Grey et al[14] suggested that despite reintervention in failed SFA intervention for long-segment disease, outcomes were poor (46% at 1 year). In a small randomized trial by van der Zaag et al,[23] reocclusion occurred in more than half of the patients randomized to percutaneous transluminal angioplasty (PTA), with an absolute risk reduction of 31% (95% confidence interval, 6%-56%) in favor of bypass surgery. The hazard ratio for occlusion comparing PTA with bypass surgery was 2.24 (95% confidence interval, 0.9-5.58).[23] Ryer et al[13] reported 45 patients with a failing or failed endoluminal intervention, of which 4% failed in the first 30 days, 78% failed between 1 and 18 months, and 18% failed after 18 months, with a mean time to failure of 8.7 months. Of these, 82% were candidates for a second endovascular procedure, 11% were suitable for a traditional open bypass, and 4% demonstrated progression of disease necessitating amputation.

Multiple modalities are available to address restenosis and occlusion after SFA intervention, including primary thrombolysis with secondary intervention, repeat conventional balloon or cutting-balloon angioplasty, stenting with conventional and drug-eluting stents, and the use of atherectomy devices to debulk the lesion.[3,4] A pilot study found cutting-balloon angioplasty failed to demonstrate superiority over conventional balloon angioplasty for treatment of femoropopliteal in-stent restenosis.[24]

Reports have demonstrated that early failure of endoluminal therapy for SFA disease is not associated with significant morbidity and mortality. Options for surgical bypass are not compromised, and the amputation level is not altered.[12] However, early failure after isolated endovascular intervention of the SFA alters the distal target in 30% of early-failure patients if open bypass is planned.[25] Bypass for failed SFA stenting has been reported by Boeckler et al,[26] and they demonstrated that these procedures are associated with high complication rates and poor outcome, including major amputations. Primary patency rates at 30 days and at 6 and 12 months were 67%, 44%, and 33%, respectively, in the poststent bypass cohort vs 98%, 96%, and 88%, respectively, in a contemporaneous group of patients treated with primary bypass grafting.[26] In our study, we found that early failure (<6 months) in the primary endo group was associated with early failure in the bypass group. The likely effectors of this observation were presentation with critical limb ischemia, worsened TASC-II lesion category, and poorer runoff.

The goal of vascular interventions is to improve symptoms, prevent limb loss, and maintain or improve quality of life. Karch et al[27] showed that most clinical failures after SFA intervention were due to anatomic failure, but a significant number occurred despite patency at the site of the SFA intervention. Although primary clinical success rates were inferior to surgical bypass graft, supplemental PTA was possible in 50% of patients.[27]

If a broader composite view of success encompassing the absence of clinical symptoms, maintenance of ambulation, and lack of a major amputation is used, only <50% of patients maintained a good outcome and it trended downward after repeat endovascular intervention and bypass. This correlated well with the findings that these groups have more critical ischemia, worse TASC-II lesions, and poor vessel tibial runoff. In bypass surgery, age, preoperative ambulatory ability, independent living status, critical limb ischemia, graft patency, and amputation predict ambulation >1 year,[28] whereas dialysis, tissue loss, age ≥75 years, and coronary artery disease are good estimates of amputation-free survival (the Edifoligide for the Prevention of Infrainguinal Vein Graft Failure [PREVENT] III Risk Score).[29]

In the current study, limb salvage was worse at 5 and 10 years with bypass than with endovascular interventions, even though patency was better. Although major amputation was not associated with graft occlusion, it was associated with presenting symptoms (rest pain and tissue loss) and poor runoff. Freedom from recurrent symptoms (recurrence of the presenting complaint or worse) is better, but this can be achieved with amputation and the patient falls out of the life table. This difference highlights the need to adopt a composite measure in reporting outcomes as it pertains to the effect on the patient's role in society.

This is a retrospective study and as such suffers from the limitations associated with such studies. This is a report of clinical practice spanning 2 decades and therefore is at the mercy of changes in surgical practice, anesthesia techniques, preoperative and postprocedural risk factors reduction, and improvements in duplex imaging. Operator experience and technology changed over time for both primary and repeat interventions, and practice patterns advanced to where more advanced lesions were treated. It is highly likely that newer modalities were used for secondary interventions because they were more prevalent and accessible. The lack of randomization allowed individual physicians' judgment to prevail, and it appears that worsening lesion category and worsening runoff prompted bypass surgery, indicating a degree of bias that would have affected the outcomes. Regardless of these weaknesses, this study does provide a window on the outcomes of reintervention after SFA interventions.

CONCLUSION

Reintervention is required in a minority of patients selected for SFA angioplasty and is associated with similar outcomes to the primary intervention. However, some of these patients do show progression of their disease, and bypass is more commonly used in these patients, with superior long-term outcomes. Early primary failure ≤6 months is linked to subsequent early failure of a subsequent bypass. This study suggests that bypass rather than repeat PTA may be the better strategy for progressive and advanced recurrent SFA disease.

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AUTHOR CONTRIBUTIONS

Conception and design: MD
Analysis and interpretation: WS, MD, JB
Data collection: EP, JN, WS, AL, MD
Writing the article: WS, AL, MD
Critical revision of the article: EP, JB, JN, WS, AL, MD
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Statistical analysis: WS, MD
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APPENDIX (ONLINE ONLY)

Methodology. For each patient captured, demographics, symptoms, existing comorbid conditions, and risk factors for atherosclerosis were identified. Risk factors for each patient were identified and corrected through his or her primary care provider. Therapy for individual patients was dictated by individual attending physician p reference and was not regulated by unit guidelines. All patients received aspirin daily (81 mg or 325 mg) as a general cardiovascular protection agent.

Noninvasive studies were performed initially; however, patients with serious symptoms or signs of severe stenosis or occlusion based on the initial noninvasive tests received angiograms. Angiograms and angiographic reports were reviewed, and lesions were described by length, calcification, and patency and then categorized under the TransAtlantic Inter-Society Consensus (TASC) II system.[1]

Preoperative distal runoff was scored by the number of patent tibial vessels and according to a modification of Society for Vascular Surgery criteria for determining bypass runoff that uses the cumulative score for the distal popliteal from the knee joint to first tibial branch (max 9 + 1) and each of the tibial vessels (max 3 each), giving a maximum possible total score of 19.

Patients were taking aspirin preoperatively, and in the last 5 years, patients also received clopidogrel preoperatively.

Angioplasty was performed under systemic heparin administration (40 to 60 U/kg), and completion angiography was performed to assess the technical result. Stents were used at the discretion of the operator primarily or as an adjunct for flow-limiting dissections, intimal flaps, or poor technical results (≥50% residual stenosis). No covered stents were used. No procedures or interventions were performed that could have potentially jeopardized the outflow vessel for a bypass.

The complexity of each intervention was scored according to the ad hoc system described by DeRubertis et al[2] in which one point was awarded for an intervention in the iliac, femoral, or tibial segments of the leg.

Patients in whom the endoluminal intervention was successful received clopidogrel (75 mg/d), and aspirin therapy was maintained at 81 mg/d. Patients who were already taking clopidogrel before the intervention continued taking it after the intervention. Clopidogrel therapy was continued for 30 days after intervention.

Patients underwent routine duplex imaging follow-up at 1, 3, and every 6 months using the criteria previously described. During follow-up, angiography was only performed if noninvasive studies suggested restenosis or occlusion (positive duplex scan with a drop in the ankle-brachial index of >0.15 and toe-brachial index of >0.1) and the patient had recurrent symptoms.

Therapy for recurrent disease. The choice of intervention was operator-dependent and there was no set protocol to manage reocclusion or stenosis during the study period. In general, restenosis after primary angioplasty or atherectomy underwent repeat angioplasty or was primarily stented. Recurrent in-stent restenosis was restented or underwent atherectomy. Bypass surgery was most often used for failed recannulization and long lesions. Endoscopic vein harvest was performed when a satisfactory vein was available. If a prosthetic graft was chosen, polytetrafluoroethylene (6 or 8 mm) or Dacron (6 or 8 mm) was used.

Definitions. Coronary artery disease was defined as a history of angina pectoris, myocardial infarction, congestive heart disease, or prior coronary artery revascularizations. Cerebrovascular disease was defined as a history of stroke, transient ischemic attack, or carotid artery revascularization.

Chronic renal impairment was defined as an estimated glomerular filtration rate <60 mL/min/1.73 m^2 or if the patient required dialysis. Hypertension was defined as a systolic blood pressure > 150 mm Hg or diastolic blood pressure > 90 mm Hg on three occasions during a 6-month period. Hypercholesterolemia was defined as fasting serum concentrations of cholesterol >200 mg/dL, a low-density lipoprotein >130 mg/dL, or triglycerides >200 mg/dL.

Diabetes was defined as a fasting plasma glucose >110 mg/dL or a hemoglobin A_{1c} level >7%. Noninsulin-dependent diabetes mellitus was defined as any patient with diabetes mellitus who did not routinely receive insulin therapy for diabetes management. Insulin-dependent diabetes mellitus was defined as any patient with diabetes mellitus who routinely received insulin therapy. Metabolic syndrome was defined as previously described[3] (insulin resistance or impaired glucose tolerance, hypertension, dyslipidemia, and abdominal obesity), with the exception of abdominal circumference, which was not routinely recorded. We substituted a body mass index score ≥30.0 kg/m^2 as a positive score instead of an abdominal circumference >102 cm for men or >88 cm for women.

TASC-II classification of disease severity for femoral lesions was used to define the categories of lesions.[1]

A death ≤30 days of the procedure was considered procedurally related. A major complication was any event, regardless of how minimal, not routinely observed after endoluminal therapy that required treatment with a therapeutic intervention or rehospitalization ≤30 days of the procedure. Systemic complications were those related to cardiac, pulmonary, renal, and sepsis. Local complications were those related to access site, surgical wounds, and the treated limb. Symptoms before and after the procedure were defined by Society for Vascular Surgery (SVS) criteria,[4] and a drop in symptom score of ≥1 in follow-up was considered as recurrent symptoms.

Lesion restenosis was classified on the basis of length of restenosis in relation to stented length. Four categories of in-stent restenosis were defined: (I) focal (≤10 mm length), (II) diffuse (>10 mm length), (III) proliferative (>10 mm length and extending outside the stent), and (IV) occlusion.

Primary, assisted primary, and secondary patency rates were defined in accordance with the reporting standards of

the SVS. Short-term clinical efficacy was achieved if all of the following occurred: absence of recurrent symptoms for 1 year, patency of the intervention until wound healing, limb salvage for 1 year, maintenance of ambulation for 1 year, and survival for 1 year. Freedom from target lesion revascularization was defined as the absence of clinically driven repeat revascularization of the target lesion (endovascular therapy for symptomatic stenosis or occlusion) or the need for surgical bypass grafting or amputation due to reocclusion of the target lesion as diagnosed by arteriography or duplex scan. Retained clinical success was defined as absence of recurrent symptoms, maintenance of ambulation, and limb preservation.

Statistical analysis. All statistical analyses were performed on an intention-to-treat basis. Measured values are reported as percentages or means ± standard deviation. Patency and limb salvage rates are calculated using Kaplan-Meier analysis and reported using current SVS criteria.[4] Standard errors are reported in Kaplan-Meier analyses. Cox proportional hazard analyses and univariate and multivariate analyses were performed to identify factors associated with outcomes. Analyses were performed using JMP 7.0 software (SAS Institute, Cary, NC).

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